

CHILD-RESISTANT PACKAGING REVIEW
Technical Review Branch

IN 12/30/97 OUT January 7, 1998

RD, TRB, Reviewed by Rosalind L. Gross January 7, 1998

EPA Reg. No. or File Symbol 9688-RGU

DP Barcode _____

EPA Petition or EUP No. _____

Date Division Received 12/30/97

Type Product(s) Insecticide (termite product)

Data Accession No(s). _____

Product Mgr./Chemical Review Mgr./Contact Person PM 03 (John Hebert)
Division RD

Product Name(s) Chemsico Insect Bait A

Company Name(s) Chemsico

Submission Purpose Examine 9 month accelerated weather CRP study (Lot Code CAD-3-46) to determine if the bait station remains CRP for the life of the product in support of CRP certification of 60 stations and any retail size in between 60 and 1 station

Active Ingredient(s), PC code, & % N-ethyl perfluorooctanesulfonamide
(sulfluramid PC code 128992) 0.01%

Summary of Findings

A December 30, 1997 label for the product indicates three possible sizes a 20, 40, or 60 bait station with a stake insertion tool. Each bait station has 0.125 oz of product, which at 0.01% sulfluramid (28.35g/oz) represents 0.354mg sulfluramid. Under the directions for use item 3 states "Inspect the stake every 2 to 3 months....every three months for the next nine months." Item 4 states "All stakes should be replaced every 9 months to maintain effectiveness." The December 30, 1997 weathering study is a 9 month study therefore the label should be changed to reflect the life of the product is 9 months. This may be accomplished by moving the last sentence of item 4 up to follow the sentence in item 3 ending "every three months for the next nine months."

The results of a 9 month accelerated weathering 50 child sequential CRP test (Lot Code CAD-3-46) giving the child one bait station at a time and a tool were a pass¹ according to the 50 child sequential test in 16 CFR 1700.20, but three children accessed one or more of the weathered bait stations. One child used a tool to access 3 bait stations, one child used her hands access 1 bait station (remove cap), and the third child used her teeth to access 1 bait station(remove cap). **The 9 month weathered station is definitely more accessible than an unweathered station and the cap, which is not supposed to be removable, was in fact removed by two children after weathering. Welding the cap onto the tube would provide an added measure of safety and is recommended. Should the bait station life be extended beyond 9 months another accelerated weathering study would have to be done to support CRP for that time period (e.g. a 12 month study for a 12 month product life).**

The CRP certification dated December 16, 1997 is acceptable. No adult testing is required for this product because an exemption from the senior adult or younger adult effectiveness specifications as described in 16 CFR 1700.15(b)(2) ease of adult opening has been granted. This exemption applies only to prefilled, nonrefillable termite insecticide bait stations that are not designed or intended to be opened or activated in a manner that exposes the contents to human contact. The exemption will be for a five year time period and applies to other products of substantially similar composition and intended uses. The product as packaged must still fully comply with all other child-resistant packaging effectiveness, compatibility, and durability standards as well as all other requirements of 40 CFR Part 157.

In conclusion, all the requirements of CRP for EPA REG # 9688-RGU have been met based on the December 11, 1997 review of MRID 444065-01 &02 supporting CRP of any number of stations between 1 and 60, the December 16, 1997 review of solubility studies (access 3255 stations to access a toxic or harmful amount equaling 5.7mg sulfluramid), and the results of the December 30, 1997 9 month accelerated weathering study (a pass according to the 50 child sequential test in 16 CFR 1700.20) along with the CRP certification. **Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to question the child resistance of the package involved.**

Company Data

A December 30, 1997 label for the product indicates three possible sizes a 20, 40, or 60 bait station (stake) with a stake insertion tool. Each bait station has 0.125 oz of product. Under the directions for use item 3 states "Inspect the stake every 2 to 3 months....every three months for the next nine months." Item 4 states "All stakes

¹A toxic or harmful amount of this product (EPA REG # 9688-RGU) is access to 5.7 mg sulfluramid (16.1 bait stations). Therefore, **a failure is opens or access to 9 bait stations.**

confirmed that the only bait stations cracked or opened were the ones reported as failures (3 bait stations by one child and 1 bait station each by two children).

The results of the 9 month accelerated weathering CRP study (Lot Code CAD-3-46) indicate that no child accessed 9 bait stations, but three children accessed one or more of the weathered bait stations. One child used a tool³ to access 3 bait stations, one child used her hands access 1 bait station (remove cap), and the third child used her teeth to access 1 bait station (remove cap). The results were a pass according to the 50 child sequential test in 16 CFR 1700.20. However, it should be noted that the **9 month weathered station is definitely more accessible than an unweathered station and the cap, which is not supposed to be removable, was in fact removed by two children after weathering. Welding the cap onto the tube would provide an added measure of safety and is recommended. Should the bait station life be extended beyond 9 months another accelerated weathering study would have to be done to support CRP for that time period (e.g. a 12 month study for a 12 month product life).**

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³Codes for method of access are the same as for MRID 444065-01 & 02 per January 6, 1998 message from registrant, Bill Metzger and January 7, 1998 telephone conversation between Rosalind L. Gross, EPA and Cindy Greene, Child Related Research, Inc.